

ENZYMATIC THERAPY

INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.Q467 ENZYMATIC THERAPY'
&
PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

What Better feels like"

April 12, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

Administration

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH
NAME Milk Thistle X [™]	Milk Thistle X contains high-quality extracts of milk thistle; dandelion, which has a secretory function in the liver; artichoke, which has a long, successful history of liver support; and licorice, which enhances the immune system and promotes the flow of bile and fat to and from the liver.*	THE CLAIM REFERS Milk Thistle (Silybum marianum) Fruit Extract, Dandelion (taraxacum officinale) Root Extract, Artichoke (Cynara scolymus) Leaf Extract, Licorice (Glycyrrhiza glabra) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

975 0162 LET 13910

By: _______Robert Doster
Title: Senior Vice President of Scientific Affairs

Date: 4/12/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer





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9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467

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April 13, 2004

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RE: Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Milk Thistle X [™]	The milk thistle extract is standardized at 80%, so each capsule provides 120 mg of silymarin, an antioxidant many times more potent than vitamins E and C.*	Milk Thistle (Silybum marianum) Fruit Extract, Dandelion (taraxacum officinale) Root Extract, Artichoke (Cynara scolymus) Leaf Extract, Licorice (Glycyrrhiza glabra) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	rie Filderlit		
•	Robert Doster		
Title:	Senior Vice President of Scientific Affairs		

Date: 4/13/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer